



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

SALZWEDEL *et al.*

Appl. No.: 10/766,528

Filed: January 29, 2004

For: **Inhibition of HIV-1 Replication
by Disruption of the Processing of
the Viral Capsid-Spacer Peptide 1
Protein**

Confirmation No.: 2237

Art Unit: 1648

Examiner: HUMPHREY, Louise Wang
Zhiying

Atty. Docket: 1900.0430002/JMC/HCC

**First Supplemental Information Disclosure Statement
Under 37 C.F.R. § 1.97(c)**

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms, PTO/SB/08A and PTO/SB/08B, are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. This First Supplemental Information Disclosure Statement is a continuation of the Applicants' Information Disclosure Statement filed on August 19, 2004 in connection with the above-captioned application.

Copies of documents NPL1 to NPL18 are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), a copy of the U.S. patent application publication, document US1, cited on the attached IDS Form, PTO/SB/08A, is not submitted. In addition, a copy of document NPL19 is not provided in accordance with the U.S. Patent and Trademark Office OG notice of October 19, 2004, which states: "the requirement in 37 C.F.R. § 1.98(a)(2)(iii) for a legible copy of the specification, including the claims, and drawings of each cited pending U.S. patent application or portion of the application

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which caused it to be listed) is sua sponte waived where the cited pending application is stored in the USPTO's IFW system."

The Examiner's attention is directed to the following co-pending U.S. Patent Application, which is directed to related technical subject matter:

U.S. National Phase Patent Application No. 11/597,431, Salzwedel *et al.*, international filing date of May 24, 2005; pending, listed as document **NPL19**.

The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent

application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. Attached is our PTO-2-38 Credit Card Payment Form in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Helene C. Carlson
Agent for Applicants
Registration No. 47,473

Date: 1/22/07

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|------------------------|----------------------------------|
| Application Number | 10/766,528 |
| Filing Date | January 29, 2004 |
| First Named Inventor | SALZWEDEL, Karl |
| Art Unit | 1648 |
| Examiner Name | HUMPHREY, Louise Wang Zhiying |
| Attorney Docket Number | 1900.0430002/JMC/HCC |

U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

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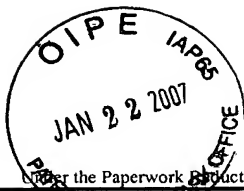
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English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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| FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | Complete if Known | |
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| | | | | Examiner Name | HUMPHREY, Louise Wang Zhiying |
| Sheet | 1 | of | 2 | Attorney Docket Number | 1900.0430002/JMC/HCC |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T ² |
| | NPL1 | Accola, M.A., <i>et al.</i> , "Efficient Particle Production by Minimal Gag Constructs Which Retain the Carboxy-Terminal Domain of Human Immunodeficiency Virus Type 1 Capsid-p2 and a Late Assembly Domain," <i>J. Virol.</i> 74:5395-5402, American Society for Microbiology (2000) | |
| | NPL2 | Adamson, C.S., <i>et al.</i> , "In Vitro Resistance to the Human Immunodeficiency Virus Type 1 Maturation Inhibitor PA-457 (Bevirimat)," <i>J. Virol.</i> , published online, doi:10.1128/JVI.01369-06, 47 pages, American Society for Microbiology (September 2006) | |
| | NPL3 | Kanamoto, T., <i>et al.</i> , "Anti-Human Immunodeficiency Virus Activity of YK-FH312 (a Betulinic Acid Derivative), a Novel Compound Blocking Viral Maturation," <i>Antimicrob. Agents Chemother.</i> 45:1225-1230, American Society for Microbiology (2001) | |
| | NPL4 | Kashiwada, Y., <i>et al.</i> , "3,28-Di-O-(dimethylsuccinyl)-betulin Isomers as Anti-HIV Agents," <i>Bioorg. Med. Chem. Lett.</i> 11:183-185, Pergamon Press (2001) | |
| | NPL5 | Li, F., <i>et al.</i> , "PA-457: A potent HIV inhibitor that disrupts core condensation by targeting a late step in Gag processing," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 100:13555-13560, National Academy of Sciences (November 2003) | |
| | NPL6 | Li, F., <i>et al.</i> , "Determinants of activity of the HIV-1 maturation inhibitor PA-457," <i>Virology</i> , published online, doi:10.1016/j.virol.2006.07.023, 8 pages, Academic Press (December 2006) | |
| | NPL7 | Liang, C., <i>et al.</i> , "Characterization of a Putative α -Helix across the Capsid-SP1 Boundary That Is Critical for the Multimerization of Human Immunodeficiency Virus Type 1 Gag," <i>J. Virol.</i> 76:11729-11737, American Society for Microbiology (November 2002) | |
| | NPL8 | Morellet, N., <i>et al.</i> , "Helical structure determined by NMR of the HIV-1 (345-392) Gag sequence, surrounding p2: Implications for particle assembly and RNA packaging," <i>Protein Sci.</i> 14:375-386, Cold Spring Harbor Laboratory Press (February 2005) | |
| | NPL9 | Pettit, S.C., <i>et al.</i> , "Replacement of the P1 Amino Acid of Human Immunodeficiency Virus Type 1 Gag Processing Sites Can Inhibit or Enhance the Rate of Cleavage by the Viral Protease," <i>J. Virol.</i> 76:10226-10233, American Society for Microbiology (October 2002) | |
| | NPL10 | Sakalian, M., <i>et al.</i> , "3-O-(3', 3' -Dimethylsuccinyl) Betulinic Acid Inhibits Maturation of the Human Immunodeficiency virus Type 1 Gag Precursor Assembled In Vitro," <i>J. Virol.</i> 80:5716-5722, American Society for Microbiology (June 2006) | |

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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| NON PATENT LITERATURE DOCUMENTS | | | |
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| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published | T ² |
| | NPL11 | Schinazi, R.F., <i>et al.</i> , "Mutations in retroviral genes associated with drug resistance," in <i>International Antiviral News</i> 496:95-107, International Medical Press (1996) | |
| | NPL12 | von Schwedler, U.K., <i>et al.</i> , "Functional Surfaces of the Human Immunodeficiency Virus Type 1 Capsid Protein," <i>J. Virol.</i> 77:5439-5450, American Society for Microbiology (May 2003) | |
| | NPL13 | Wieggers, K., <i>et al.</i> , "Sequential Steps in Human Immunodeficiency Virus Particle Maturation Revealed by Alterations of Individual Gag Polyprotein Cleavage Sites," <i>J. Virol.</i> 72:2846-2854, American Society for Microbiology (1998) | |
| | NPL14 | Zhou, J., <i>et al.</i> , "Small-Molecule Inhibition of Human Immunodeficiency Virus Type 1 Replication by Specific Targeting of the Final Step of Virion Maturation," <i>J. Virol.</i> 78:922-929, American Society for Microbiology (January 2004) | |
| | NPL15 | Zhou, J., <i>et al.</i> , "The sequence of the CA-SP1 junction accounts for the differential sensitivity of HIV-1 and SIV to the small molecule maturation inhibitor 3-O-{3',3'-dimethylsuccinyl}-betulinic acid," <i>Retrovirology</i> 1:15, published on-line, doi:10.1186/1742-4690-1-15, 25 pages, BioMed Central (June 2004) | |
| | NPL16 | Zhou, J., <i>et al.</i> , "The Specificity of the Small-Molecule Maturation Inhibitor 3-O-{3',3'-Dimethylsuccinyl}-Betulinic Acid for HIV-1 is Determined by the Sequence of the CA-SP1 Junction of GAG," poster 26, presented at the Fifth HIV DRP Symposium: Antiviral Drug Resistance, Chantilly, VA (November 2004) | |
| | NPL17 | Zhou, J., <i>et al.</i> , "Inhibition of HIV-1 Maturation via Drug Association with the Viral Gag Protein in Immature HIV-1 Particles," <i>J. Biol. Chem.</i> 280:42149-42155, American Society for Biochemistry and Molecular Biology (December 2005) | |
| | NPL18 | Zhou, J., <i>et al.</i> , "HIV-1 Resistance to the Small Molecule Maturation Inhibitor 3-O-{3',3'-dimethylsuccinyl}-betulinic acid is Conferred by a Variety of Single Amino Acid Substitutions at the CA-SP1 Cleavage Site in Gag," <i>J. Virol.</i> , published online, doi:10.1128/JVI.01626-06, 17 pages, American Society for Microbiology (October 2006) | |
| | NPL19 | U.S. National Phase Patent Application No. 11/597,431, Salzwedel <i>et al.</i> , international filing date of May 24, 2005 (NOT PUBLISHED) | |

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